ISRCTN64352175 https://doi.org/10.1186/ISRCTN64352175

# The impact of indocyanine green (ICG) angiography in multiple diagnostic imaging for the management of exudative age-related macular degeneration (ARMD): a single blind prospective randomised controlled trial of fluorescein angiography vs FA & ICG

| | | |
|---|---|---|
| **Submission date**<br>30/09/2005 | **Recruitment status**<br>Stopped | [ ] Prospectively registered<br>[ ] Protocol<br>[ ] Statistical analysis plan<br>[ ] Results<br>[ ] Individual participant data<br>[ ] Record updated in last year |
| **Registration date**<br>30/09/2005 | **Overall study status**<br>Stopped | |
| **Last Edited**<br>07/04/2011 | **Condition category**<br>Eye Diseases | |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

**Contact name**
Dr Sergio Pagliarini

**Contact details**
Paybody Eye Unit
Coventry & Warwickshire Hospital
Stoney Stanton Road
Coventry
United Kingdom
CV1 4FH
+44 (0)24 7696 6496
sergio.pagliarini@uhcw.nhs.uk

## Additional identifiers

**Protocol serial number**

N0295142266

# Study information

### Scientific Title

### Study objectives
Attempt to identify ophthalmic features and positive predictive value for ICG as 'diagnosis and management modifier'. The use of indocyanine gren angiography (ICG) may facilitate the identification of lesions that have been proposed to respond to laser treatment.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Not provided at time of registration

### Study design
Prospective randomised controlled trial and pilot study

### Primary study design
Interventional

### Study type(s)
Not Specified

### Health condition(s) or problem(s) studied
Eye Diseases: Age-related macular degeneration (ARMD)

### Interventions
Interventions are fluorescein angiography compared with fluorescein angiography and indocyanine green angiography.

Added 05/09/2008: trial was stopped due to new treataments available.

### Intervention Type
Other

### Phase
Not Specified

### Primary outcome(s)
Moderate and severe visual loss defined as loss of three lines or 15 letters (doubling of visual angles) and loss of 6 lines or 30 letters respectively, on a log MAR visual acuity chart, at 4,8 and 12 months.

### Key secondary outcome(s))
1. ICG rates modification of fluorescein based diagnosis and management
2. Specificity and sensitivity of ophthalmic signs predictive of ICG findings

**Completion date**
24/05/2006

**Reason abandoned (if study stopped)**
New treatments available

# Eligibility

**Key inclusion criteria**
240 patients, of whom 24 are estimated to have retinal angiomatous proliferation (RAP).

**Participant type(s)**
Patient

**Healthy volunteers allowed**
No

**Age group**
Not Specified

**Sex**
Not Specified

**Key exclusion criteria**
No specific exclusion criteria

**Date of first enrolment**
24/05/2004

**Date of final enrolment**
24/05/2006

# Locations

**Countries of recruitment**
United Kingdom

England

**Study participating centre**
**Paybody Eye Unit**
Coventry
United Kingdom
CV1 4FH

# Sponsor information

**Organisation**
Department of Health

# Funder(s)

**Funder type**
Government

**Funder Name**
University Hospitals Coventry and Warwickshire NHS Trust (UK), NHS R&D Support Funding

# Results and Publications

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**
Not provided at time of registration